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| 10/522,810 | 09/20/2005 | Vernon L. Alvarez | 2006636-0011 | 9490 |
| 24280 7590 11/23/2009 CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110 | | | | |
| EXAMINER | | | | |
| LUKTON, DAVID | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1654 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@choate.com

Office Action Summary

Application No.

10/522,810

Applicant(s)

ALVAREZ ET AL.

Examiner

DAVID LUKTON

Art Unit

1654

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 13 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-49 is/are pending in the application.
- 4a) Of the above claim(s) 45, 46, 48 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-44 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Pursuant to the response filed 8/13/09, claim 42 has been amended. Claims 42-49 remain pending. Claims 42-44 and 47 are examined in this Office action; claims 45, 46 and 49 are withdrawn.

Applicants' arguments filed 8/13/09 have been considered and found not persuasive.

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Applicants have traversed the withdrawal of claim 49. However, the elected peptide is TTDHQMARS, and despite at least two opportunities to do so, applicants have declined to identify any label. Instead, what applicants have done is to attempt to transform the issue of restriction/election into an issue of enablement. The examiner would agree that, given a suggestion to do so, the peptide chemist of ordinary skill would be able to "label" a peptide, absent undue experimentation. But the fact that this may be true has nothing to do with the issue of election/restriction. Given that applicants have declined to identify any label, and none is apparent, the examiner is fully justified in withdrawing claim 49 from consideration.

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The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42-44 and 47 rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method, yet no objective of the method is recited. As such, all objectives are encompassed. For example, treatment of any and all diseases would be encompassed, such as AIDS, Alzheimers disease, pancreatic cancer, lung cancer, hypertension, psoriasis, alopecia, and obesity. In traversing, applicants are invited to provide a few examples of diseases which they believe are not encompassed. This will form the basis for further discussion.

And it's not only treatment of diseases (human or animal) that are encompassed. Inhibition of any biochemical process would be encompassed, as would augmentation of any biochemical process. And even if were true that biochemical processes could be inhibited by the peptides of SEQ ID NO:13, this would actually constitute evidence that augmentation of a biochemical process (any such process) would lack enablement.

In addition to the foregoing, the claims would encompass a method of treating a disease in a human merely by adding a peptide to a Petri dish. Even applicants would not argue that such a thing is possible. And yet, there is nothing in claim 42 to preclude this possibility.

As long as the claims encompass methods of using chlorotoxin (*per se*), there will be an argument to be made that a method of treating glioblastoma (in a mammal) would be

enabled, and perhaps treatment of prostate cancer as well. But as the claims currently stand, the vast majority of embodiments (that are encompassed) lack enablement.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

Clearly, "undue experimentation" would be required to practice even a small fraction of the embodiments that are encompassed.

In response to the foregoing, applicants have argued that the objective of a method is irrelevant to the question of enablement, and that an examiner is barred from weighing any aspect of the claim language other than the process steps. Applicants, however, are not correct. Consider the following two claims:

100. A method of preventing or curing AIDS, Alzheimer's Disease or pancreatic cancer comprising the step of administering compound "X" to a patient in need thereof.

101. A method comprising the step of administering compound "X" to a patient in need thereof.

That is, suppose that a given applicant had shown that compound "X" binds to a particular receptor or that compound X inhibits a particular enzyme; and that he submits an application with the two claims above (100 and 101). Certainly, it is highly

unlikely that the demonstration of the binding of compound X to a receptor or the inhibition of an enzyme would be sufficient to justify a finding of enablement for claim 100. (Applicants may or may not be willing to concede this point). But the more important point here is that the degree of enablement of claim 101 is no higher than that of claim 100, and indeed, is significantly lower. Claim 101 encompasses each of the objectives that claim 100 encompasses, and many more. So the fact that all objectives are encompassed by a claim does not make the claim more enabled than a claim that recites just a few specific objectives. The foregoing analysis can even be pushed further with the following example:

102. A method of achieving perpetual motion comprising the following steps:

- a) getting out of bed in the morning;*
- b) driving a car to a laboratory;*
- c) creating a device that comprises a spinning means.*

103. A method comprising the following steps:

- a) getting out of bed in the morning;*
- b) driving a car to a laboratory;*
- c) creating a device that comprises a spinning means.*

No doubt applicants would argue that claim 103 is enabled. But applicants would be incorrect in adopting such a rhetorical posture, as this claim encompasses the objective of claim 102.

The rejection is maintained.

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Claims 42-44 and 47 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 42 now recites the following:

“the polypeptide does not comprise full length chlorotoxin”.

Applicants are requested to point to the page and line number where support can be found.

▲

The following is a quotation of 35 USC, §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter

and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 42-44 and 47 are rejected under 35 U.S.C. §103 as being unpatentable over Soroceanu (*Cancer Research* **58**, 4871-79, 1998) in view of Lippens (*Biochemistry* **34**, 13-21, 1995) or DeBin (*Am J Physiol* **264**, C361-C369, 1993).

Soroceanu discloses use of chlorotoxin to target brain tumors. Soroceanu does not provide the sequence of chlorotoxin. Each of Lippens and DeBin provide the sequence of chlorotoxin, which is the following:

MCMPCFTTDHQMARKCDDCCGGKGRGKCYGPQCLCR

Claim 42 now recites that “the polypeptide does not comprise full length chlorotoxin”.

However, there are multiple ways in which this limitation can be met. One of the ways, of course, is for the polypeptide to consist of fewer than 36 amino acids.

(Claim 42 still does not clearly and explicitly mandate this). Another way for the requirements of claim 42 to be met is for the polypeptide to comprise, or consist of something other than chlorotoxin itself. As it happens, many such peptides are obvious. If, for example, one were to substitute glutamic acid for one of the aspartic acid residues, one would have a peptide which is not chlorotoxin. Or a substitution of

Asn for Gln, or Val for Leu, or ornithine for lysine. Being close structural homologs differing by just one methylene unit, one would expect substantially identical pharmacological activity for two otherwise identical peptides which differ in just one side chain. Thus, any of several peptides are rendered obvious by the references, and which would circumvent the requirement that chlorotoxin itself be excluded.

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Claims 42-44 and 47 are rejected under 35 U.S.C. §103 as being unpatentable over Soroceanu (*Cancer Research* **58**, 4871-79, 1998).

Soroceanu discloses use of chlorotoxin to target brain tumors.

The same argument as above applies here as well. The rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

/David Lukton/

Primary Examiner, Art Unit 1654